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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/7055,145 04/03/96 WEEKS

D 0553-18

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HM12/0130

EXAMINER

KRUSE, D

ART UNIT

PAPER NUMBER

1638

13

DATE MAILED:

01/20/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	09/055,145	Weeks et al
	<b>Examiner</b>	<b>Art Unit</b>
	David H Kruse	1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
  - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1)  Responsive to communication(s) filed on \_\_\_\_ .

2a)  This action is **FINAL**.                    2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4)  Claim(s) 1-49 is/are pending in the application.  
4a) Of the above claim(s) 8-20,25-35,40-43,45,46 and 49 is/are withdrawn from consideration.

5)  Claim(s) \_\_\_\_\_ is/are allowed.

6)  Claim(s) 1-7,21-24,36-39,44,47 and 48 is/are rejected.

7)  Claim(s) \_\_\_\_\_ is/are objected to.

8)  Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

11)  The proposed drawing correction filed on \_\_\_\_\_ is: a)  approved b)  disapproved.

12)  The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. § 119**

- 13)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).  
a)  All b)  Some \* c)  None of:  
1.  Certified copies of the priority documents have been received.  
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 15)  Notice of References Cited (PTO-892) 18)  Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_  
16)  Notice of Draftsperson's Patent Drawing Review (PTO-948) 19)  Notice of Informal Patent Application (PTO-152)  
17)  Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6 and 7 20)  Other: \_\_\_\_\_

## DETAILED ACTION

### ***Election/Restrictions***

1. Applicant's election without traverse of Claim 1-7, 21-24, 36-39, 44, 47 and 48 in Paper No. 12, filed 21 December 2000 is acknowledged.
2. Claims 8-20, 25-35, 40-43, 45, 46 and 49 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 12.
3. This application contains claims 8-20, 25-35, 40-43, 45, 46 and 49 drawn to an invention nonelected with traverse in Paper No. 12. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.
4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

### ***Oath/Declaration***

5. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because: Non-initialed and/or non-dated alterations have been made to the oath or declaration. See 37 CFR 1.52(c). Specifically, the address for Inventor Donald P. Weeks.

***Drawings***

6. This application has been filed with informal drawings, which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed.

***Claim Objections***

7. Claims 2, 3, 5 and 6 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***Claim Rejections - 35 USC § 112***

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 1, 4, 7, 21, 24, 36, 39, 44, 47 and 48 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant claims a transgenic host cell comprising a nucleic acid sequence encoding a dicamba-degrading oxygenase, a transgenic plant comprising said nucleic

acid sequence, a method of controlling weeds with a transgenic plant and methods of selecting transformed plant cells and plants.

Applicant describes a nucleic acid sequence designated SEQ ID NO: 3 that encodes the amino acid sequence of a dicamba-degrading oxygenase designated SEQ ID NO: 4.

Applicant does not describe the composition or structure of other nucleic acid sequences encoding a dicamba-degrading oxygenase, nor does Applicant describe a transgenic host cell or a transgenic plant which is tolerant to dicamba comprising a nucleic acid sequence encoding a dicamba-degrading oxygenase.

Hence, it is unclear from the instant specification that Applicant was in possession of the invention as broadly claimed.

10. Claims 39, 44, 47 and 48 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicant claims a transgenic host cell comprising a nucleic acid sequence encoding a dicamba-degrading oxygenase, a transgenic plant comprising said nucleic acid sequence, a method of controlling weeds with a transgenic plant and methods of selecting transformed plant cells and plants.

Applicant teaches the isolation of a nucleic acid sequence designated SEQ ID NO: 3 that encodes the amino acid sequence of an oxygenase designated SEQ ID NO: 4.

Applicant does not teach a transgenic host cell or a transgenic plant which is tolerant to dicamba comprising a nucleic acid sequence encoding a dicamba-degrading oxygenase nor does Applicant teach methods of selecting transgenic plant that are tolerant to dicamba or a method of weed control comprising said transgenic plant.

*In re Wands*, 858F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988) lists eight considerations for determining whether or not undue experimentation would be necessary to practice an invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claims.

The state of the art for modification of gene expression or of phenotypic characteristics in plants by genetic transformation is highly unpredictable and hence significant guidance is required to practice the art without undue experimentation. The specific effects of given promoters, leaders, DNA sequences, and terminator sequences on gene expression in transformed plants can not be anticipated reliably and must be determined empirically (Koziel *et al*, Plant Mol. Biol. 32:393-405, 1996, abstract, pp.402-403). In addition, the effect of a transgene on the phenotype of a transformed plant is unpredictable and requires extensive guidance for one of ordinary skill in the art to practice the claimed invention (Yuan *et al*, Current Opinion in Biotechnology 1997, 8:227-233, page 231, Conclusions). As Applicant has not taught a plant, transformed with a nucleotide sequence encoding a dicamba-degrading oxygenase that has

herbicidal resistance, it would require undue experimentation by one of ordinary skill in the art to practice Applicant's invention as broadly claimed.

If Applicant were able to overcome this rejection, the instant Claims would be subject to the Scope of Enablement rejection as set forth below (Item 11).

11. Claims 1, 4, 7, 21, 24, 36, 39, 44, 47 and 48 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the DNA molecule of SEQ ID NO: 3, encoding the dicamba-degrading oxygenase of SEQ ID NO: 4, does not reasonably provide enablement for any DNA molecule encoding a dicamba-degrading oxygenase. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Applicant claims an isolated DNA molecule that encodes a dicamba-degrading oxygenase, a DNA construct comprising said DNA molecule, a vector comprising said DNA construct and cells and plants comprising said vector.

Applicant teaches an isolated DNA molecule (SEQ ID NO: 3) that encodes the *Pseudomonas maltophilia* DI-6 dicamba-degrading oxygenase (SEQ ID NO: 4).

Applicant does not teach any other isolated DNA molecules that encode a dicamba-degrading oxygenase.

The teachings of *Wands* are given above.

The state of the art for DNA isolation requires guidance as to what sequences are critical for probe and PCR nucleotide sequence recovery methods, PCR reaction conditions and hybridization conditions as well as the nucleotide sequences which are

critical for expressing a dicamba-degrading oxygenase required to practice Applicant's invention. Applicant admits at page 54, lines 3-6, that Applicant's SEQ ID NO: 3 only showed a 33.8% homology to another oxygenase component of a vanillate demethylase. Applicant does not teach a method of identifying and isolating all other oxygenase components of demethylases that degrade dicamba. In the absence of such guidance one of ordinary skill in the art would require undue experimentation to screen through a myriad of nucleotide sequences to identify those that encode a dicamba-degrading oxygenase that would confer upon a transgenic plant tolerance to a dicamba-herbicide when compared to a non-transformed plant.

12. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

13. Claims 1-7, 21-24, 36-39, 44, 47 and 48 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

At Claims 1, 2, 4, 5, 21, 22 and 36, the phrase "coding for" should read -- encoding --.

At Claims 22 and 37, the phrase "codes for" should read -- encodes --.

At Claim 7, the phrase "a vector." is indefinite in view of the scope of the invention. The phrase -- a transformation vector -- is suggested.

At Claims 21 line 2 and 36 line 3, the phrase "linked to" is unclear as it is not known if the "expression control sequences" are linked to the host cell/plant or the DNA coding for a dicamba-degrading oxygenase.

At Claim 39, the term "tolerant" is relative and does not state the metes and bounds of the claimed invention.

Claims 44, 47 and 48 are indefinite because said claims are dependent upon a nonelected invention.

At Claim 47 line 7, the term "growing" should read -- culturing -- because cells in culture grow and divide.

At Claim 47 line 9, the phrase "will grow" should read -- proliferate --, and at line 10 the phrase "will not grow" should read -- do not proliferate --. Claims should be worded in present tense.

Claim 47 is indefinite because the "method of selecting" lacks a selecting step. Appropriate correction is required.

At Claim 48 line 5 the phrase "will grow" should read -- grow --, and at line 6 the phrase "will be" should read -- is --.

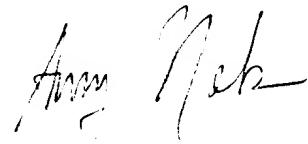
At Claim 48 line 2, the phrase "suspected of" is indefinite.

14. The Claims are free of the prior art because the prior art does not teach or suggest a nucleotide sequence that encodes an oxygenase component of a demethylase that degrades dicamba.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David H. Kruse, Ph.D. whose telephone number is (703) 306-4539. The examiner can normally be reached on Monday to Friday from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. Paula Hutzell can be reached at (703) 308-4310. The fax phone number for this Group is (703) 308-4242 or (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Yolanda Vines whose telephone number is (703) 305-2365.



AMY J. NELSON, PH.D  
PRIMARY EXAMINER

David H. Kruse, Ph.D.  
24 January 2000